

CLAIMS

1-67. (Cancelled)

68. (New) An electrochemical test strip for conducting testing for the concentration of glucose in a blood sample, comprising:

a strip body including an edge extending about the perimeter of said strip body, said strip body defining a capillary channel and a vent in fluid communication with the capillary channel, said strip body comprising a sample application port open at a location along the edge, the capillary channel extending from the sample application port to at least the vent;

at least working and counter electrodes spaced from each other and positioned within the capillary channel at a location spaced from the perimetric edge;

a test reagent adjacent at least the working electrode; and

visualization means associated with the capillary channel for enabling a user to visually identify when a sufficient amount of blood sample has been added to the capillary fill chamber to accurately perform a test, said visualization means including a solid, transparent or translucent viewing material extending from at least adjacent the sample application port and overlying at least a portion of the capillary channel including said working electrode and at least a portion of said counter electrode,

said visualization means further includes a fill line extending across the capillary channel at a location intermediate the length of the capillary channel at a position such that movement of the blood sample to the fill line indicates sufficient filling of the test strip for conducting a test.

69. (New) The test strip of claim 68 in which said fill line is formed by an opaque portion overlying a portion of the capillary test chamber.

70. (New) The test strip of claim 69 in which the fill line extends at a location between the working electrode and the vent.

71. (New) The test strip of claim 70 in which said fill line is formed by an opaque portion overlying a portion of the capillary test chamber.

72. (New) The test strip of claim 68 in which said strip body includes opposed sides of the capillary channel, the sides being parallel and extending in a straight line from the sample application port, and orthogonal to the perimetric edge, to at least one of the electrodes, the fill line extending across the capillary channel in an orientation orthogonal to the opposed sides of the test strip.

73. (New) The test strip of claim 72 in which said strip body further includes opaque portions generally aligned with the opposed sides of the capillary channel from adjacent the sample application port to at least one of the electrodes.

74. (New) The test strip of claim 73 in which the opaque portions are spaced apart to reveal greater than about 75% of the width of the capillary channel.

75. (New) The test strip of claim 68 in which said strip body includes a first substrate, a second substrate and a roof, the second substrate being positioned intermediate the first substrate and the roof and including an opening, the opening of the second substrate together with the first substrate and the roof defining the capillary channel.

76. (New) The test strip of claim 75 in which said test strip includes conductive tracks connected with said working and counter electrodes, the first substrate having first and second surfaces, the working and counter electrodes being affixed to the first surface of the first substrate, the second substrate having first and second surfaces and an opening, the second surface of the second substrate being affixed to the first surface of the first substrate,

the second substrate configured to expose a portion of the conductive tracks for electrical connection to a meter capable of measuring an electrical property, the opening being located along a perimetric edge of the second substrate and exposing said electrodes, and a roof having first and second surfaces and including a solid, transparent or translucent viewing material, the second surface of the roof being affixed to the first surface of the second substrate and positioned so that it overlays the opening of the second substrate and so that the second surface of the roof and the first surface of the first substrate form opposing walls of the capillary channel, the transparent or translucent viewing material extending from at least adjacent to the sample application port and overlying the entire width of one of the electrodes and at least about ten percent of the width of the other electrode.

77. (New) The test strip of claim 75 in which the second substrate defines opposed sides of the capillary channel, the sides being parallel and extending in a straight line from the sample application port, and orthogonal to the perimetric edge, to at least one of the electrodes.

78. (New) The test strip of claim 77 in which said test strip further includes opaque portions generally aligned with the opposed sides of the capillary channel from adjacent the sample application port to at least one of the electrodes, the fill line extending across the capillary channel in an orientation orthogonal to the opposed sides of the test strip.

79. (New) The test strip of claim 78 in which the opaque portions are defined by the roof.

80. (New) The test strip of claim 75 in which the opening of the second substrate defines opposed sides of the capillary channel, said visualization means including opaque portions generally aligned with the opposed sides of the capillary channel extending from

adjacent the sample application port to at least one of the electrodes, the opaque portions being located in the area adjacent the capillary channel, the opaque portions having a color which contrasts with the color of the sample as observed through the viewing material,

whereby a user is able to visually locate the sample within the capillary channel by observation through the viewing material and is able to determine when the sample has filled the capillary channel at least up to the fill line.

81. (New) The test strip of claim 80 in which the opposed sides of the capillary channel are parallel and extend in a straight line from the sample application port, and orthogonal to the perimetric edge, to at least one of the electrodes, and the fill line extends across the capillary channel in an orientation orthogonal to the opposed sides of the test strip.

82. (New) An electrochemical test strip for conducting testing for the concentration of an analyte in a blood sample, comprising:

a strip body including an edge extending about the perimeter of said strip body, said strip body defining a capillary channel and a vent in fluid communication with the capillary channel, said strip body comprising a sample application port open at a location along the edge, the capillary channel extending from the sample application port at least to the vent;

at least working and counter electrodes spaced from each other and positioned within the capillary channel at a location spaced from the perimetric edge; and

a test reagent adjacent at least the working electrode;

said strip body defining a viewing area allowing continuous visualization of the capillary channel from a portion thereof at or generally adjacent the sample application port, up to and including said working electrode and at least a portion of said counter electrode,

the viewing area being positioned and dimensioned such that blood introduced to the

capillary channel through the sample application port and filling the viewing area at least up to a portion of said counter electrode under the viewing area is required for the test strip to have a sufficient blood sample to conduct a test.

said strip body further including a fill line extending across the viewing area at a location intermediate the length of the capillary channel at a position such that movement of the blood sample to the fill line indicates sufficient filling of the test strip for conducting a test.

83. (New) The test strip of claim 82 in which said fill line is formed by an opaque portion overlying a portion of the capillary test chamber.

84. (New) The test strip of claim 83 in which the fill line extends at a location between the working electrode and the vent.

85. (New) The test strip of claim 84 in which said fill line is formed by an opaque portion overlying a portion of the capillary test chamber.

86. (New) The test strip of claim 82 in which said strip body includes opposed sides of the capillary channel, the sides being parallel and extending in a straight line from the sample application port, and orthogonal to the perimetric edge, to at least one of the electrodes, the fill line extending across the capillary channel in an orientation orthogonal to the opposed sides of the test strip.

87. (New) The test strip of claim 86 in which said strip body further includes opaque portions generally aligned with the opposed sides of the capillary channel from adjacent the sample application port to at least one of the electrodes.

88. (New) The test strip of claim 87 in which the opaque portions are spaced apart to reveal greater than about 75% of the width of the capillary channel.

89. (New) The test strip of claim 82 in which said strip body includes a first substrate, a second substrate and a roof, the second substrate being positioned intermediate the first substrate and the roof and including an opening, the opening of the second substrate together with the first substrate and the roof defining the capillary channel.

90. (New) The test strip of claim 89 in which said test strip includes conductive tracks connected with said working and counter electrodes, the first substrate having first and second surfaces, the working and counter electrodes being affixed to the first surface of the first substrate, the second substrate having first and second surfaces and an opening, the second surface of the second substrate being affixed to the first surface of the first substrate, the second substrate configured to expose a portion of the conductive tracks for electrical connection to a meter capable of measuring an electrical property, the opening being located along a perimetric edge of the second substrate and exposing said electrodes, and a roof having first and second surfaces and including a solid, transparent or translucent viewing material, the second surface of the roof being affixed to the first surface of the second substrate and positioned so that it overlays the opening of the second substrate and so that the second surface of the roof and the first surface of the first substrate form opposing walls of the capillary channel, the transparent or translucent viewing material extending from at least adjacent to the sample application port and overlying the entire width of one of the electrodes and at least about ten percent of the width of the other electrode.

91. (New) The test strip of claim 89 in which the second substrate defines opposed sides of the capillary channel, the sides being parallel and extending in a straight line from the

sample application port, and orthogonal to the perimetric edge, to at least one of the electrodes.

____ 92. (New) The test strip of claim 91 in which said test strip further includes opaque portions generally aligned with the opposed sides of the capillary channel from adjacent the sample application port to at least one of the electrodes, the fill line extending across the capillary channel in an orientation orthogonal to the opposed sides of the test strip.

____ 93. (New) The test strip of claim 92 in which the opaque portions are defined by the roof.

____ 94. (New) The test strip of claim 89 in which the opening of the second substrate defines opposed sides of the capillary channel, said visualization means including opaque portions generally aligned with the opposed sides of the capillary channel extending from adjacent the sample application port to at least one of the electrodes, the opaque portions being located in the area adjacent the capillary channel, the opaque portions having a color which contrasts with the color of the sample as observed through the viewing material,

____ whereby a user is able to visually locate the sample within the capillary channel by observation through the viewing material and is able to determine when the sample has filled the capillary channel at least up to the fill line.

____ 95. (New) The test strip of claim 94 in which the opposed sides of the capillary channel are parallel and extend in a straight line from the sample application port, and orthogonal to the perimetric edge, to at least one of the electrodes, and the fill line extends across the capillary channel in an orientation orthogonal to the opposed sides of the test strip.

____ 96. (New) An electrochemical test strip for conducting testing for the concentration of glucose in a blood sample, comprising:

a strip body including an edge extending about the perimeter of said strip body, said strip body defining a capillary channel and a vent in fluid communication with the capillary channel, said strip body comprising a sample application port open at a location along the perimetric edge, the capillary channel extending from the sample application port to at least the vent, said strip body further defining a test area along the capillary channel between the sample application port and the vent;

at least working and counter electrodes spaced from each other and positioned within the test area of the capillary channel at a location spaced from the perimetric edge;

a test reagent received within the test area of the capillary channel and adjacent at least the working electrode;

said strip body including a solid, transparent or translucent viewing material overlying at least a portion of the capillary channel, including from a portion thereof at or generally adjacent the sample application port continuously up to and including said working electrode and at least a portion of said counter electrode, the viewing material permitting visualization of the blood sample as it moves through the capillary channel to the test area;

said strip body further including opaque portions defining a fill area viewable through the viewing material, the fill area comprising an area of the capillary channel needed to be filled to conduct an accurate test; and

a fill line extending across the capillary channel at a location intermediate the length of the capillary channel at a position such that movement of the blood sample to the fill line indicates sufficient filling of the test strip for conducting a test.

wherein observation through the viewing material of the blood sample within the capillary channel up to said electrodes comprises confirmation of sufficient blood sample being introduced into the capillary channel to conduct a test.

97. (New) The test strip of claim 96 in which said fill line is formed by an opaque portion overlying a portion of the capillary test chamber.

98. (New) The test strip of claim 96 in which the fill line extends at a location between the working electrode and the vent.

99. (New) The test strip of claim 98 in which said fill line is formed by an opaque portion overlying a portion of the capillary test chamber.

100. (New) The test strip of claim 96 in which the fill line extends at a location between the test area and the vent.

101. (New) The test strip of claim 100 in which said fill line is formed by an opaque portion overlying a portion of the capillary test chamber.

102. (New) The test strip of claim 96 in which the opaque portions are sized and dimensioned such that the blood sample is required to fill up to the fill line the portion of the capillary channel viewable through the viewing material in order to have a sufficient amount of blood sample to conduct a test.

103. (New) The test strip of claim 96 in which the opaque portions extend continuously in alignment with the opposed sides of the capillary channel from the perimetric edge to the electrodes.

104. (New) The test strip of claim 96 in which the opaque portions are sized and dimensioned such that the blood sample is required to fill up to the fill line the portion of the

capillary channel viewable through the viewing material in order to have a sufficient amount of blood sample to conduct a test.